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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/942,515	08/29/2001	Raghbir S. Bhullar	RDID 00108US	8155
32842	7590	12/24/2003	EXAMINER	
THE LAW OFFICE OF JILL L. WOODBURN, L.L.C. JILL L. WOODBURN 128 SHORE DR. OGDEN DUNES, IN 46368			OLSEN, KAJ K	
		ART UNIT	PAPER NUMBER	
		1753		

DATE MAILED: 12/24/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>
	09/942,515	BHULLAR ET AL.
	<b>Examiner</b>	<b>Art Unit</b>
	Kaj Olsen	1753

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 26 November 2003.
- 2a) This action is FINAL.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-32 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 1-32 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. §§ 119 and 120

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All    b) Some \* c) None of:
1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 13) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
- a) The translation of the foreign language provisional application has been received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

#### Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO-1449) Paper No(s) 1/27.8/29.
- 4) Interview Summary (PTO-413) Paper No(s) \_\_\_\_\_.
- 5) Notice of Informal Patent Application (PTO-152)
- 6) Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Claim Rejections - 35 USC § 112***

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 1-24 and 30-32 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

3. In claims 1, 13, and 30, it is unclear what the metes and bounds of a “discernible” code pattern would be. Discernible by what and discernible for what purpose? The full scope of what could reasonably be construed as being a “discernable code” by one possessing ordinary skill in the art is unclear.

4. Claim 13 is further indefinite because it is unclear what a “sufficient contrast” would be when the applicant hasn’t specified what kind of discernment is being utilized.

5. Claim 30 is further indefinite because applicant first sets forth the presence of a “mean for identifying” and later refers to it as being an “identifying means”. Although the examiner can recognize that the applicant is referring to the same thing in each case, this is potentially confusing because means-plus-function language can be interpreted with different scope than function-means language. Applicant should be consistent in the use of the term “means” to avoid any confusion.

***Specification***

6. The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

The following title is suggested: Biosensor with deposited code pattern.

***Claim Rejections - 35 USC § 102***

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

8. Claims 1, 4-19, 22-24, 30, and 31 are rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Kawanaka et al (USP 6,599,406 B1).

9. Kawanaka discloses a biosensor comprising a support substrate with electrodes and a pattern of terminals that are utilized for the determination of details about the biosensor (fig. 12 and 13 and col. 17, line 51 through col. 19, line 31). Because the layout of the pattern varies depending on the type of sensor present (e.g. compare figures 12, 13, and 15), this pattern thereby reads on the applicants “discernible” pattern or the means for identifying the biosensor giving the claim language its broadest reasonable interpretation. Kawanaka also discloses the presence of a reagent (col. 10, lines 8-21). With respect to the code pattern and electrode being defined by the same electrically conductive coating, the determination of

patentability for the claim is based on the product itself. Because the product of the claim is identical to the invention of Kawanaka the process from which it was made is the same as or obvious over the process utilized by Kawanaka (see *In re Thorpe*, 777 F.2d 695, 698). However, it appears that the code pattern is deposited as the same time as the electrodes.

10. With respect to the pattern being electrically discernible, the various terminals on the test strip are for electrically interacting with the measuring apparatus.

11. With respect to the pattern being optically discernible, because the terminals are carbon and the substrate is not, the pattern would clearly be optically discernible (i.e. the naked eye could distinguish where carbon is and is not deposited). Although the reference doesn't state the use of optical discernment, that is only the intended use of the apparatus and the intended use need not be given further due consideration in determining patentability. The pattern only need be optically discernible.

12. With respect to the recess, the gap between electrodes 5 and 6 in fig. 33 would constitute a recess in the conductive coating.

With respect to the presence of a second conductive coating, because this limitation is an extension of a process of making the coating pattern (which was not given further due consideration as set forth above) and because this limitation doesn't specify the second coating must be compositionally different from the first coating, this limitation would read on the mere use of a second coating step where the same electrode ink is deposited a second time. Again the determination of patentability for the claim is based on the product itself. Because the product of the claim is identical to the invention of Kawanaka the process from which it was made is the same as or obvious over the process utilized by Kawanaka (see *In re Thorpe*, 777 F.2d 695, 698).

13. With respect to the use of a cover, see fig. 33 and 34.
14. With respect to the code patterns being either isolated or interconnected, the various embodiments of fig. 12, 13, 15, 20, 22, 24, and 28-32 all teach combinations of both.

***Claim Rejections - 35 USC § 103***

15. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

16. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

17. Claims 3 and 21 (and claims 5 and 15 in the alternative) are rejected under 35 U.S.C. 103(a) as being unpatentable over Kawanaka in view of Song et al (USP 5,567,302).

18. Kawanaka set forth all the limitations of claims 3 and 21, but did not explicitly set forth the use of gold for the conductive coating. However, the use of noble metals such as gold are well known in the art of biosensors because these metals are highly conductive, but still inert in biological fluid. In particular, Song teaches that gold or carbon (which was utilized by

Art Unit: 1753

Kawanaka) both find utility for electrode materials (col. 19, lines 1-16). It would have been obvious to one of ordinary skill in the art at the time the invention was being made to utilize the teaching of Song for the biosensor of Kawanaka both because the substitution of one known electrode material for another requires only routine skill in the art and because gold provides high conductivity and inertness.

19. With respect to claims 5 and 15 in the alternative, Song teaches that when gold is to be utilized as an electrode (which was obvious to utilized as suggested above), the gold should be the second conductive layer deposited (chromium should be deposited first for adhesion purposes)(col. 16, lines 30-43). Hence, it would have been obvious to one of ordinary skill in the art at the time the invention was being made to deposit two conductive layers such that the electrode layer has good adhesion to the substrate.

***Allowable Subject Matter***

20. Claims 2, 20, and 32 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, second paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

21. The following is a statement of reasons for the indication of allowable subject matter: Although the prior art recognizes the inclusion of barcodes onto electrode containing biosensors (e.g. see Poppe et al references), the prior art does not disclose nor render obvious a bar code defined by the electrically conductive coating utilized to define the electrodes.

***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kaj Olsen whose telephone number is (703) 305-0506. The examiner can normally be reached on Monday through Thursday from 7:00 AM-4:30 PM. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner are unsuccessful, the examiner's supervisor, Mr. Nam Nguyen, can be reached at (703) 308-3322.

When filing a fax in Group 1700, please indicate in the header "Official" for papers that are to be entered into the file, and "Unofficial" for draft documents and other communications with the PTO that are not for entry into the file of this application. This will expedite processing of your papers. The fax number for regular communications is (703) 305-3599 and the fax number for after-final communications is (703) 305-5408.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist, whose telephone number is (703) 308-0661.



Kaj K. Olsen  
Patent Examiner  
AU 1753  
December 13, 2003